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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,814

06/06/2005

Yoshiki Sawa

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5468

757 7590 10/09/2007
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EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,814

Applicant(s)

SAWA ET AL.

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-29 and 89-94, drawn to a decellularized tissue.

Group II, claim(s) 30-53, drawn to a method of decellularizing tissue.

Group III, claim(s) 54-88 and 95, drawn to methods of using a decellularized tissue to regenerate, treat or provide prophylactic treatment to tissue *in vivo*.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature which is shared by all three Inventive Groups is the decellularized tissue, per se. However, claim 1, at least, is anticipated by Livesey et al (US Patent 5,336,616). Livesey et al disclose decellularized tissues. The decellularized tissues are devoid of native cells, and thus have a cell survival rate which is 'less than a level at which an immune reaction is elicited in an organism'; additionally, the decellularized tissue retains an intact basement membrane for attachment of cells, and provides an extracellular protein and collagen matrix which can be remodeled and repaired by host cells (See Livesey et al, col 4, ln 39-55), each of which are considered to be 'function[s] which were possessed by the tissue when the tissue was not decellularized'. Consequently, the special technical feature which links Inventive Groups I-III fails to provide a contribution over the prior art, and thus unity of invention is lacking.

Additionally, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. Type of tissue:

- a) blood vessels, a type of luminal tissue (claims 8, 9, 15, 43, 66, 69, 86)
- b) blood vessel-like tissue (claim 9, 15, 43, 66, 69, 86)
- c) cardiac valves (claim 9, 15, 43, 66, 69, 86)
- d) pericardia (claim 9, 15, 43, 66, 69, 86)
- e) dura mater (claim 9, 15, 43, 66, 69, 86)
- f) corneas (claim 9, 15, 43, 66, 69, 86)
- g) bones (claim 9, 15, 43, 66, 69, 86)
- h) membrane-like tissue (claims 24-29)

2. Type of cell to be added to the decellularized tissue:

- i) vascular endothelial cells, which is also a blood vessel cell (claims 23, 61, 68)
- j) smooth muscle cells, which is a blood vessel cell (claim 23, 61, 68)
- k) fibroblasts, which is also a blood vessel cell (claim 23, 61, 68)
- l) blood cells (claim 23)
- m) precursor cells (claim 23)
- n) somatic stem cells capable of differentiating (claim 23)
- o) blood-vessel like cells (claims 61, 68)

3. Type of amphipathic molecule used in decellularization process:

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p) 1,2-epoxide polymer (claim 33)

q) PEG (claims 34-38)

Applicant is required, in reply to this action, to elect a single species from EACH of the THREE (3) groups above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art recognized equivalents.

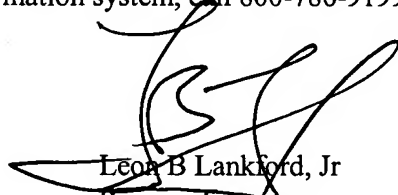
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B Lankford, Jr
Primary Examiner
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